

### **REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks. Applicants sincerely thank the Examiner and her supervisor for holding a personal interview with Applicants' representative on May 6, 2008. The Examiner and her supervisor's kind advice have been incorporated into this reply.

#### **I. CLAIM STATUS AND AMENDMENTS**

Claims 2-7 were pending in this application when last examined and stand rejected. It is noted that on page 2 of the Office Action, different claims are indicated as pending. The Examiner is requested to clarify the pending claims in the next Office Action.

Claim 6 is amended to clarify the claimed invention.

Claim 7 is also amended in conformance with the amendments to claim 6.

Claims 2-5 are newly cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a divisional or continuation application on any cancelled subject matter.

No new matter has been added.

#### **II. WRITTEN DESCRIPTION REJECTION**

In item 2 on pages 3-9, claims 2-7 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection as applied to the amended claims.

Applicants note that claim 6, as amended, is directed towards the F3 fraction of soluble outer membrane proteins of 18 to 27kD from the merozoite of *Eimeria acervulina*. Applicants further note that this "F3" fraction is shown in Example 1 and is well-known in the art. For example, Lillehoj et al. (cited by the Examiner) describes the F3 fraction. Thus, Applicants respectfully suggest this concern of the Examiner is overcome.

Furthermore, claim 6 has been amended to recite "antibodies" obtained by the noted method. Applicants note that the recited method includes a defined protein fraction, i.e. F3, to create the antibodies.

Finally, Applicants' note that this amendment to claim 6 conforms with the discussions during the personal interview of May 6, 2008. In particular, Applicants now suggest that the

claimed antibodies, created from a defined fraction, meet the written description requirement. In other words, a person of skill in the art would understand that the inventors have possession of the claimed antibodies.

Applicants further note that "preventing" has been deleted from the claims.

Thus, for the above noted reasons, Applicants suggest that this rejection, as applied to the amended claims, is untenable and should be withdrawn.

### III. OBVIOUSNESS REJECTION

In item 3 on pages 9-12, claims 2 and 4 were again rejected under 35 U.S.C. § 103(a) as obvious over Lillehoj et al. in view of Wells et al.

Applicants note that these claims have been cancelled in order to expedite allowance and therefore this rejection is moot.

Furthermore, in regard to claims 6-7, which were not part of this rejection, Applicants note that Lillehoj et al. discloses an 18 to 27kD native protein fraction (F3) from *Eimeria acervulina* merozoites and a monoclonal antibody against the protein. However, Lillehoj et al. only disclose oral immunization of chickens with F3 (i.e. antigen) and never describes oral administration of an antibody against the antigen. In particular, it is described on page 385, left column, 13<sup>th</sup> line from the bottom of this reference that "in experiment, 3-wk-old chickens were twice immunized orally ... with ... recombinant 3-1 protein, then challenged ... with ... *E. acervulina* oocysts." Thus, in this experiment, the chickens were orally administered with the antigen, not with the antibody.

Therefore, Lillehoj et al. discloses active immunity (cellular immunity) but the present invention relates to an oral passive immunity (humoral immunity). Please see, for example, the following web sites: ([http://en.wikipedia.org/wiki/Passive\\_immunity](http://en.wikipedia.org/wiki/Passive_immunity)) and (<http://en.wikipedia.org/wild/Cellularimmunity>).

Applicants note that it was common general technical knowledge in this field at the time of filing that passive immunity is quite different from the active immunity (i.e. vaccination) both in procedure and mechanism. It was believed that only active immunity was effective for

coccidiosis and passive immunity was not effective before the present invention (please see, Infection and Immunity, July 1987, vol. 55, no. 7, p. 1616-1621, attached to the December 11, 2007 response). The present inventors were found for the first time that chicken coccidiosis can be effectively treated by orally administering the chicken egg antibodies (polyclonal antibodies) of the present invention (i.e., by passive immunity).

Applicants note there is a significant disadvantage to using avian coccidium live vaccine. In particular, the chicken farm is left contaminated. On the other hand, inactivated vaccines produce insufficient amounts of antibody for preventing the infection, and are not sufficiently effective. It is also to be noted that, avian coccidium live vaccine needs a period of several weeks before production of protective antibody after chicks are immunized. This period is far too long for use in broiler chicks (see page 3 lines 13-21 of the present specification).

In addition, monoclonal antibodies, in particular, monoclonal antibodies which can protect a bird from three *Eimeria* species, are expensive to produce. Therefore, in manufacture of a composition for administering to birds, monoclonal antibodies are not industrially applicable. On the other hand, the present inventors have surprisingly found that by orally administering to birds chicken egg polyclonal antibodies, the birds can be protected against three *Eimeria* species. Thus, Applicants note claims 6-7 are not obvious.

#### IV. CLAIM OBJECTION

Claim 2 was objected to because of the noted informality in item 4 on page 12. This claim is cancelled and therefore this objection is moot.

#### V. INDEFINITENESS REJECTION

In item 5 on page 12-13, claims 2-7 were newly rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully traverse this rejection as applied to the amended claims.

In regard to the term “immunogenicity,” Applicants note such term has been deleted in order to expedite allowance and therefore this part of the rejection is moot.

In regards to the phrase “the soluble outer membrane protein F3 from the merozoite of *Eimeria acervulina*, which is a fraction of soluble outer membrane proteins of 18 to 27kD.”,

Applicants note such term has been amended to indicate that F3 is a protein fraction. Such amendment was suggested during the interview. Thus, Applicants believe this part of the rejection has been overcome.

Finally, in regard to the indefiniteness of the term "F3", Applicants note that claim 6 has been amended to clarify the meaning of this term. Furthermore, Applicants note that such term is well-known in the art as evidenced by Lillehoj et al. as well as by Example 1 of the specification. Further, Applicants note that such term was indicated as definite during the interview. Thus, Applicants suggest that this part of this rejection is overcome.

For the above-noted reasons, Applicants suggest that this rejection, as applied to the amended claims, is untenable and should be withdrawn.

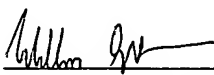
**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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